Minutes of Meeting

Alabama Medicaid Agency
Pharmacy and Therapeutics Committee

November 10, 2010

Members Present: Chairman, Dr. Chivers Woodruff, Dr. Julia Boothe, Dr. Gerard Ferris, Dr. Kelli Littlejohn, Mr. Ben Main, Dr. Robert Moon, Ms. LaTonage Porter, and Dr. James Yates

Members Absent: Ms. Janet Allen and Dr. Lucy Culpepper

Presenters: Dr. Tina Hisel

Presenters Present via Teleconference: Dr. Laureen Biczak

1. OPENING REMARKS

Dr. Woodruff called the Pharmacy and Therapeutics (P&T) Committee Meeting to order at 9:07 a.m. He introduced two new members, Dr. Julia Boothe and Dr. James Yates.

2. APPROVAL OF MINUTES

Chairman Woodruff asked if there were any corrections to the minutes from the August 11, 2010 P&T Committee Meeting.

There were no objections. Mr. Main made a motion to approve the minutes as presented and Dr. Yates seconded to approve the minutes. The minutes were unanimously approved.

3. PHARMACY PROGRAM UPDATE

An ALERT was sent to providers on September 17, 2010 regarding a change in pharmacy reimbursement. The Agency moved to an Average Acquisition Cost (AAC) reimbursement for drug ingredient cost, plus a modified dispensing fee, for outpatient pharmacy claims effective September 22, 2010.

An ALERT was sent to providers on September 27, 2010 providing clarification on physician-administered drugs which are compounded.

In October 2010, the Agency implemented an on-line drug look-up tool. A search will show drug coverage status, reimbursement rates, maximum units, prior authorization (PA) status, and preferred drug status.

Dr. Littlejohn noted that a routine Preferred Drug List (PDL) update was completed on October 1, 2010.

An ALERT was sent to providers on November 5, 2010 regarding National Correct Coding Initiative (NCCI) edits, which pertain to non-pharmacy claims.

An ALERT was sent to providers on November 8, 2010 regarding the use of old Medicaid ID numbers. The Agency is phasing out the acceptance of old Medicaid ID number beginning with "000". All new Medicaid ID numbers begin with a "5". The Agency will deny any claims received on or after January 17, 2011 that are submitted with the old Medicaid ID number.

Dr. Littlejohn stated that this is the last week of Commissioner Steckel's tenure at the Alabama Medicaid Agency. She will be leading the health care reform efforts in Louisiana. Dr. Littlejohn thanked the Commissioner for her tenure with the Agency and her work within the State.

Dr. Littlejohn noted that Dr. Michelle Freeman has resigned from the P&T Committee. A replacement will be nominated by MASA. She welcomed Dr. Julia Boothe and Dr. James Yates to the committee.

Effective January 1, 2011, the Alabama Board of Pharmacy will no longer provide continuing education credit for P&T Committee Meeting attendance. According to the Board of Pharmacy, acceptable continuing education must be accredited by ACPE. The Agency is not an ACPE-approved entity. The Agency will continue to provide continuing medical education (CME) credit. Pharmacists will receive a certificate for attendance; however, this may not be approved by the Alabama Board of Pharmacy for their continuing education requirements.

4. ORAL PRESENTATIONS BY MANUFACTURERS/MANUFACTURERS' REPRESENTATIVES

Five-minute verbal presentations were made on behalf of pharmaceutical manufacturers. The process and timing system for the manufacturers' oral presentations was explained. The drugs and corresponding manufacturers are listed below with the appropriate therapeutic class. There were a total of five manufacturer verbal presentations at the meeting.

5. PHARMACOTHERAPY CLASS RE-REVIEWS (Please refer to the website for full text reviews.)

The pharmacotherapy class reviews began at approximately 9:15 a.m. There were a total of nineteen re-reviews and two new drug reviews. The antihypertensive agents were previously reviewed in September 2008.

Dr. Hisel stated that the European Society of Hypertension guidelines were updated in 2009. According to this guideline, thiazide diuretics, ACE inhibitors, calcium-channel blockers, angiotensin II receptor antagonists, and β-blockers do not differ in their ability to lower blood

pressure. There is no evidence that these major drug classes differ in their ability to protect against overall cardiovascular risk or cause-specific cardiovascular events. There were no other changes in the hypertension guidelines since these classes were last reviewed. Dr. Hisel commented that the JNC-8 guidelines are expected to be released in the Fall of 2011.

Dr. Ferris commented that the magnitude of blood pressure lowering is more important for cardiovascular risk reduction than the use of a specific antihypertensive agent. However, certain agents have compelling indications for use, despite similar effects on blood pressure. Dr. Hisel stated she would highlight the compelling indications for use during her review.

Central Alpha-Agonists: American Hospital Formulary Service (AHFS) 240816
Manufacturer comments on behalf of these products:
None

Dr. Hisel stated that the central alpha-agonists that are included in this review are listed in Table 1. They are approved for the treatment of hypertension and all of the agents are available in a generic formulation. There have been no major changes in the prescribing information, treatment guidelines or clinical studies since this class was last reviewed.

Therefore, all brand central alpha-agonists within the class reviewed are comparable to each other and to the generics and OTC products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand central alpha-agonist is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Dr. Woodruff asked the P&T Committee Members to mark their ballots.

Direct Vasodilators: AHFS 240820
Manufacturer comments on behalf of these products:
None

Dr. Hisel stated that the direct vasodilators that are included in this review are listed in Table 1. They are approved for the treatment of heart failure and hypertension, as well as for the treatment of hypoglycemia due to hyperinsulinism. Current treatment guidelines that incorporate the use of the direct vasodilators are summarized in Table 2. The heart failure guidelines have been updated since this class was last reviewed. Hydralazine and isosorbide dinitrate have been used off-label for many years to treat heart failure. Guidelines currently recommend the use of hydralazine and an oral nitrate in patients who do not tolerate an ACE inhibitor or angiotensin II receptor antagonist. The fixed-dose combination of isosorbide dinitrate and hydralazine is FDA-approved for the treatment of heart failure as an adjunct to standard therapy in self-identified black patients. In the A-HeFT trial, the use of this combination product improved mortality, prolonged the time to hospitalization, and improved functional status compared to placebo. The patients in this trial were also receiving standard heart failure therapy, including ACE inhibitors, angiotensin II receptor

antagonists, β-blockers, diuretics, digoxin and spironolactone. The Heart Failure Society of America, the American College of Cardiology and the American Heart Association recommend the use of the fixed-dose combination of isosorbide dinitrate and hydralazine in African American patients with NYHA functional class III or IV heart failure who are on a standard regimen including an ACE inhibitor or angiotensin II receptor antagonist and a β-blocker. Both hydralazine and isosorbide dinitrate are available generically; however, generic hydralazine is not available in a strength equivalent to the fixed-dose combination product.

There have been no other major changes in the prescribing information, treatment guidelines or clinical studies. Hydralazine and minoxidil are approved for the treatment of hypertension and both agents are available in a generic formulation. No specific recommendation is made in the hypertension guidelines regarding the use of the direct vasodilators. Diazoxide is considered a first-line treatment option for hypoglycemia due to hyperinsulinism and it is not available in a generic formulation.

Therefore, all brand direct vasodilators within the class reviewed are comparable to each other and to the generics and OTC products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use. The fixed-dose combination of isosorbide dinitrate and hydralazine (BiDil®) should be available through the medical justification portion of the prior authorization process as an adjunct to standard heart failure therapy in self-identified black patients. Due to its limited FDA-approved indications, diazoxide (Proglycem®) should be managed through the existing medical justification portion of the prior authorization process.

No brand direct vasodilator is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Dr. Woodruff asked the P&T Committee Members to mark their ballots.

Peripheral Adrenergic Inhibitors: AHFS 240832
Manufacturer comments on behalf of these products:
None

Dr. Hisel stated that reserpine is the only peripheral adrenergic inhibitor in this class and it is available in a generic formulation. There have been no major changes in the prescribing information, treatment guidelines or clinical studies since this class was last reviewed.

Therefore, all brand peripheral adrenergic inhibitors within the class reviewed are comparable to each other and to the generics and OTC products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand peripheral adrenergic inhibitor is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Dr. Woodruff asked the P&T Committee Members to mark their ballots.

Hypotensive Agents, Miscellaneous: AHFS 240892
Manufacturer comments on behalf of these products:
None

Dr. Hisel stated that there are currently no covered outpatient drugs available in the miscellaneous hypotensive agents class. Injectable fenoldopam is the only agent that is currently available. It is indicated for the in-hospital, short-term management of severe hypertension. Oral mecamylamine was previously included in this review; however, as of September 30, 2010, there are no longer any covered NDCs for this product.

No brand miscellaneous hypotensive agent is recommended for preferred status. Alabama Medicaid should continue to include AHFS Class 240892 in the PDL screening process. If new outpatient miscellaneous hypotensive agents are added, it is recommended that this class be re-reviewed at that time.

There were no further discussions on the agents in this class. Dr. Woodruff asked the P&T Committee Members to mark their ballots.

Alpha-Adrenergic Blocking Agents: AHFS 242000
Manufacturer comments on behalf of these products:
None

Dr. Hisel stated that the alpha-adrenergic blocking agents that are included in this review are listed in Table 1. They are approved for the treatment of benign prostatic hyperplasia (BPH) and hypertension. All of the products are available in a generic formulation. There have been no major changes in the prescribing information, treatment guidelines or clinical studies since this class was last reviewed.

Therefore, all brand alpha-adrenergic blocking agents within the class reviewed are comparable to each other and to the generics and OTC products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand alpha-adrenergic blocking agent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Dr. Ferris commented that the 5-α reductase inhibitors can alter the natural history of symptomatic BPH, whereas alpha blockers only treat symptoms.

Dr. Yates commented that there is a new combination product containing a 5-α reductase inhibitor and an alpha blocker.

There were no further discussions on the agents in this class. Dr. Woodruff asked the P&T Committee Members to mark their ballots.

Beta-Adrenergic Blocking Agents: AHFS 242400
Manufacturer comments on behalf of these products:
None

Dr. Hisel stated that the β-adrenergic blocking agents that are included in this review are listed in Table 1. All of the agents are available in a generic formulation with the exception of nebivolol and penbutolol. Current treatment guidelines that incorporate the use of the beta-adrenergic blocking agents are summarized in Table 3. Due to improvements in morbidity and mortality, guidelines recommend the use of a β-blocker in patients with acute coronary syndromes, angina, arrhythmias, coronary artery disease, heart failure, hypertension, left ventricular dysfunction, and post-myocardial infarction. They are also recommended as one of several initial options for the prevention of migraine headaches, as well as for the treatment of essential tremor. Comparative studies have demonstrated similar efficacy among the β-blockers for the treatment of hypertension and angina.

There is insufficient evidence to support that one brand beta-adrenergic blocking agent is safer or more efficacious than another. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

Therefore, all brand beta-adrenergic blocking agents within the class reviewed are comparable to each other and to the generics and OTC products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand beta-adrenergic blocking agent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Dr. Ferris asked if there was any data to support the use of one particular β-blocker over another for the treatment of post-myocardial infarction. Dr. Hisel stated that several β-blockers have been studied and are approved to reduce cardiovascular mortality in patients who have survived a myocardial infarction, including atenolol, metoprolol, propranolol, and timolol. Dr. Ferris also commented that only certain β-blockers are approved for the treatment of heart failure, including bisoprolol, carvedilol and metoprolol.

There were no further discussions on the agents in this class. Dr. Woodruff asked the P&T Committee Members to mark their ballots.

Dihydropyridines: AHFS 242808
Manufacturer comments on behalf of these products:
Exforge® - Novartis

Dr. Hisel stated that the dihydropyridines that are included in this review are listed in Table 1. Amlodipine is available in combination with benazepril, olmesartan, valsartan, and

valsartan/hydrochlorothiazide. It should be noted that the amlodipine/telmisartan fixed-dose combination product is classified by AHFS as an angiotensin II receptor antagonist; therefore, it is included in that class review. The fixed-dose combination of amlodipine/valsartan/hydrochlorothiazide and clevidipine (an injectable product primarily administered in an institution) were approved by the FDA since this class was last reviewed. All of the single entity dihydropyridines are available in a generic formulation, as well as the amlodipine/benazepril fixed-dose combination product.

The dihydropyridines are approved for the treatment of angina and hypertension. Amlodipine has also been approved by the FDA to reduce the risk of hospitalization due to angina and to reduce the risk of a coronary revascularization procedure in patients with recently documented coronary artery disease. There have been no major changes in the treatment guidelines regarding the use of the dihydropyridines since this class was last reviewed.

The dihydropyridines have been shown to favorably affect cardiovascular morbidity and mortality. Numerous clinical trials have shown that the dihydropyridines can effectively lower systolic and diastolic blood pressure when administered alone or in combination with other agents. In studies comparing combination therapy to monotherapy, the more aggressive treatment regimens lowered blood pressure to a greater extent than the less-intensive treatment regimens. Some comparative trials have demonstrated slight differences in blood pressure effects among the various dihydropyridines; however, the clinical significance of these differences remains to be established. Most patients will require more than one antihypertensive agent to achieve blood pressure goals. The use of a fixed-dose combination product may simplify the treatment regimen and improve adherence. However, there are no prospective, randomized trials that have demonstrated better clinical outcomes with a fixed-dose combination product compared to the coadministration of the individual components as separate formulations.

There is insufficient evidence to support that one brand dihydropyridine is safer or more efficacious than another. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

Therefore, all brand dihydropyridines within the class reviewed are comparable to each other and to the generics and OTC products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand dihydropyridine is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Dr. Woodruff asked the P&T Committee Members to mark their ballots.

Calcium-Channel Blocking Agents, Miscellaneous: AHFS 242892
Manufacturer comments on behalf of these products:
None

Dr. Hisel stated that diltiazem and verapamil are the only miscellaneous calcium-channel blocking agents in this class and they are approved for the treatment of angina, arrhythmias and hypertension. They are available in a variety of modified-release delivery systems that alter their pharmacokinetic properties, including onset and duration of action. Both agents are available in a generic formulation. There have been no major changes in the prescribing information, treatment guidelines or clinical studies since this class was last reviewed. Both agents have been shown to reduce mortality and cardiovascular event rates.

There is insufficient evidence to support that one brand miscellaneous calcium-channel blocking agent is safer or more efficacious than another. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

Therefore, all brand miscellaneous calcium-channel blocking agents within the class reviewed are comparable to each other and to the generics and OTC products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand miscellaneous calcium-channel blocking agent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Dr. Woodruff asked the P&T Committee Members to mark their ballots.

Angiotensin-Converting Enzyme Inhibitors: AHFS 243204
Manufacturer comments on behalf of these products:
None

Dr. Hisel stated that the ACE inhibitors that are included in this review are listed in Table 1. They are available as single entity products, as well as in combination with hydrochlorothiazide or verapamil. All of the products are available in a generic formulation.

Current treatment guidelines that incorporate the use of the ACE inhibitors are summarized in Table 2. Guidelines recommend the use of an ACE inhibitor in patients with acute coronary syndrome, cerebrovascular disease, coronary artery disease, diabetes, diabetic nephropathy, heart failure, hypertension, left ventricular dysfunction, left ventricular hypertrophy, previous myocardial infarction and non-diabetic renal disease. In general, guidelines do not give preference to one ACE inhibitor over another.

In clinical trials, the ACE inhibitors have been shown to reduce cardiovascular morbidity and mortality, preserve renal function in patients with nephropathy, and effectively lower blood pressure when administered as monotherapy or in combination with other antihypertensive agents.

There is insufficient evidence to support that one brand angiotensin-converting enzyme inhibitor is safer or more efficacious than another.

Therefore, all brand ACE inhibitors within the class reviewed are comparable to each other and to the generics and OTC products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand ACE inhibitor is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Dr. Woodruff asked the P&T Committee Members to mark their ballots.

Angiotensin II Receptor Antagonists: AHFS 243208
Manufacturer comments on behalf of these products:
None

Dr. Hisel stated that the angiotensin II receptor antagonists that are included in this review are listed in Table 1. They are available as single entity products, as well as in combination with hydrochlorothiazide. The fixed-dose combination of telmisartan/amlodipine was approved by the FDA since this class was last reviewed. Tribenzor® (olmesartan, amlodipine and hydrochlorothiazide) is a fixed-dose combination product that was added to Medicaid's drug file in August 2010 and will not be included in this review. Alabama Medicaid's policy states that drugs must be commercially available for a minimum of 180 days to be eligible for inclusion in a PDL review. Losartan and losartan/hydrochlorothiazide are the only angiotensin receptor antagonists that are available in a generic formulation.

Current treatment guidelines that incorporate the use of the angiotensin II receptor antagonists are summarized in Table 2. Guidelines recommend the use of an ACE inhibitor or angiotensin II receptor antagonists in patients with cerebrovascular disease, coronary artery disease, heart failure, hypertension, left ventricular dysfunction, left ventricular hypertrophy, diabetes, diabetic nephropathy, previous myocardial infarction and renal disease. Some of the guidelines specifically recommend the use of ACE inhibitors as initial therapy, with the subsequent use of angiotensin II receptor antagonists in patients who do not tolerate ACE inhibitors. Guidelines do not give preference to one angiotensin II receptor antagonists over another for the treatment of hypertension.

Numerous clinical trials have shown that the angiotensin II receptor antagonists can effectively lower blood pressure, administered alone or in combination with other antihypertensive agents. Some comparative trials have demonstrated slight differences in blood pressure effects among the various angiotensin II receptor antagonists; however, the clinical significance of these differences remains to be established. Most patients will require more than one antihypertensive agent to achieve blood pressure goals. The use of a fixed-dose combination product may simplify the treatment regimen and improve adherence. However, there are no prospective, randomized trials that have demonstrated better clinical outcomes with a fixed-dose combination product compared

to the coadministration of the individual components as separate formulations. Angiotensin II receptor antagonists have been shown to reduce cardiovascular morbidity and mortality, as well as preserve renal function. The use of losartan also decreases the risk of stroke in patients with hypertension and left ventricular hypertrophy. It should be noted that the ACE inhibitors have also been shown to positively impact these endpoints as well. Several studies comparing angiotensin II receptor antagonists and ACE inhibitors have demonstrated similar efficacy with regards to cardiovascular events, heart failure and the rate of progression of nephropathy. ACE inhibitors inhibit the breakdown of bradykinin, which may lead to the development of a persistent non-productive cough. The angiotensin II receptor antagonists do not increase bradykinin and may be better tolerated in some patients.

The FDA is evaluating data from two clinical trials in which patients with type 2 diabetes who were taking olmesartan had a higher rate of death from cardiovascular causes compared to those who were taking placebo. The FDA's review is ongoing and no conclusions have been made. A meta-analysis suggested that the use of angiotensin II receptor antagonists may be associated with a small increased risk of cancer; however, the FDA has not concluded that these agents increase the risk of cancer, and they believe that the benefits continue to outweigh their potential risks.

At this time, there is insufficient evidence to conclude that the angiotensin II receptor antagonists offer a significant clinical advantage over other alternatives in general use. Therefore, all brand angiotensin II receptor antagonists within the class reviewed are comparable to each other and to the generics and OTC products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand angiotensin II receptor antagonist is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Dr. Yates asked about the controversy surrounding the use of an ACE inhibitor and angiotensin II receptor antagonist in combination. Dr. Hisel commented that although studies have been conducted, the routine use of these agents in combination is not recommended. The use of an angiotensin II receptor antagonist with a renin inhibitor is acceptable.

Dr. Moon asked GHS if other States require failure with an ACE inhibitor prior to the approval of an angiotensin II receptor antagonist. Dr. Biczak stated that there are several States that have established that criteria. Dr. Moon stated that Alabama Medicaid does not require failure with an ACE inhibitor prior to approving an angiotensin II receptor antagonist.

Dr. Ferris commented that there is no evidence, other than the development of a cough, to prefer an ACE inhibitor over an angiotensin II receptor antagonist.

There were no further discussions on the agents in this class. Dr. Woodruff asked the P&T Committee Members to mark their ballots.

Mineralocorticoid (Aldosterone) Receptor Antagonists: AHFS 243220
Manufacturer comments on behalf of these products:
None

Dr. Hisel stated that the mineralocorticoid (aldosterone) receptor antagonists that are included in this review are listed in Table 1. They are all approved for the treatment of hypertension. Eplerenone is also indicated to improve survival in patients with left ventricular systolic dysfunction (ejection fraction ≤40%) and clinical evidence of congestive heart failure after an acute myocardial infarction. Spironolactone is approved for the management of hyperaldosteronism, hypokalemia, and edema associated with congestive heart failure, cirrhosis, or the nephrotic syndrome. It is also indicated for patients with severe heart failure (NYHA class III – IV) to increase survival, and to reduce the need for hospitalization for heart failure when used in addition to standard therapy. All of the products are available in a generic formulation.

Current treatment guidelines that incorporate the use of the aldosterone antagonists are summarized in Table 2. For the treatment of heart failure, an aldosterone antagonist is recommended in patients with severe symptoms and an LVEF ≤35%. Therapy should be in addition to an ACE inhibitor or angiotensin II receptor antagonist and β-blocker. An aldosterone antagonist is also recommended following a myocardial infarction in patients with an LVEF ≤40% who also have either diabetes or heart failure, in addition to an ACE inhibitor and β-blocker. For the treatment of cirrhosis and ascites, spironolactone is recommended as first-line therapy in addition to sodium restriction. Spironolactone is also recommended for the treatment of patients with unilateral primary aldosteronism in lieu of surgery, and in those with bilateral adrenal disease. Eplerenone is considered an alternative treatment option, especially in men who experience erectile dysfunction and gynecomastia with spironolactone therapy. There have been no other major changes in the treatment guidelines since this class was last reviewed.

The aldosterone antagonists effectively lower blood pressure. Eplerenone and spironolactone have also been shown to reduce cardiovascular morbidity and mortality in patients with heart failure when added to standard therapy. Several studies in diabetic and non-diabetic patients with renal disease have demonstrated a reduction in proteinuria with the addition of spironolactone to existing ACE inhibitor and/or angiotensin II receptor antagonist therapy.

There is insufficient evidence to support that one brand aldosterone antagonist is safer or more efficacious than another. Therefore, all brand mineralocorticoid (aldosterone) receptor antagonists within the class reviewed are comparable to each other and to the generics and OTC products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand mineralocorticoid (aldosterone) receptor antagonist is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Dr. Woodruff asked the P&T Committee Members to mark their ballots.

Renin Inhibitors: AHFS 243240
Manufacturer comments on behalf of these products:
Tekturna® - Novartis
Valturna® - Novartis

Dr. Hisel stated that aliskiren is the only renin inhibitor in this class and it is approved for the treatment of hypertension. It is available as a single entity product, as well as in combination with hydrochlorothiazide or valsartan. The fixed-dose combination of aliskiren/valsartan was approved by the FDA since this class was last reviewed. Tekamlo® (aliskiren and amlodipine) is a fixed-dose combination product that was added to Medicaid's drug file in September 2010 and will not be included in this review. Alabama Medicaid's policy states that drugs must be commercially available for a minimum of 180 days to be eligible for inclusion in a PDL review. There are no generic products currently available.

Current treatment guidelines that incorporate the use of the renin inhibitors are summarized in Table 2. Aliskiren was approved by the FDA in 2007, and the fixed-dose combination products were subsequently approved in 2008 (Tekturna HCT®) and 2009 (Valturna®). Therefore, the guidelines do not provide specific recommendations regarding the use of these agents. All of the available guidelines consistently recommend that the selection of an antihypertensive agent be based on compelling indications for use.

Several clinical trials have shown that aliskiren, aliskiren/hydrochlorothiazide, and aliskiren/valsartan effectively lower blood pressure. The reduction in blood pressure with aliskiren monotherapy was similar to monotherapy with ACE inhibitors, angiotensin II receptor blockers, β-blockers and dihydropyridines. In clinical trials comparing combination therapy to monotherapy, the more aggressive treatment regimen lowered blood pressure to a greater extent than the less-intensive treatment regimen. Aliskiren has been shown to have positive effects on surrogate markers of cardiovascular and renal damage in patients with type 2 diabetes and nephropathy, heart failure and left ventricular hypertrophy. However, the effects of aliskiren on hard cardiovascular and renal endpoints have not been established. There are several outcomes trials currently underway with aliskiren.

At this time, there is insufficient evidence to conclude that the renin inhibitors offer a significant clinical advantage over other alternatives in general use. Therefore, all brand renin inhibitors within the class reviewed are comparable to each other and to the generics and OTC products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand renin inhibitor is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Dr. Woodruff asked the P&T Committee Members to mark their ballots.

At 10:05 a.m., Dr. Woodruff called for a 10 minute break. The meeting resumed at 10:15 a.m.

Loop Diuretics: AHFS 402808
Manufacturer comments on behalf of these products:
None

Dr. Hisel stated that the loop diuretics that are included in this review are listed in Table 1. They are approved for the treatment of edema and hypertension. Bumetanide, furosemide and torsemide are available in a generic formulation. There have been no major changes in the treatment guidelines, prescribing information, or clinical studies since this class was last reviewed.

Therefore, all brand loop diuretics within the class reviewed are comparable to each other and to the generics and OTC products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand loop diuretic is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Dr. Woodruff asked the P&T Committee Members to mark their ballots.

Potassium-Sparing Diuretics: AHFS 402816
Manufacturer comments on behalf of these products:
None

Dr. Hisel stated that the potassium-sparing diuretics that are included in this review are listed in Table 1. They are approved for the treatment of congestive heart failure, edema and hypertension. All of the products are available in a generic formulation. There have been no major changes in the prescribing information, treatment guidelines or clinical studies since this class was last reviewed.

Therefore, all brand potassium-sparing diuretics within the class reviewed are comparable to each other and to the generics and OTC products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand potassium-sparing diuretic is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Dr. Woodruff asked if amiloride was the only single-entity agent in this class. Dr. Hisel confirmed that amiloride was the only single-entity agent in the class.

Dr. Ferris commented that often clonidine or loop diuretics are used to treat significantly elevated blood pressure; however, the loop diuretics may be associated with fewer adverse events.

There were no further discussions on the agents in this class. Dr. Woodruff asked the P&T Committee Members to mark their ballots.

Thiazide Diuretics: AHFS 402820
Manufacturer comments on behalf of these products:
None

Dr. Hisel stated that the thiazide diuretics that are included in this review are listed in Table 1. They are approved for the treatment of hypertension and edema due to renal dysfunction. They are also approved as adjunctive therapy for the management of edema associated with congestive heart failure, hepatic cirrhosis, as well as corticosteroid and estrogen therapy. All of the agents are available in a generic formulation. There have been no major changes in the treatment guidelines, prescribing information, or clinical studies since this class was last reviewed.

Therefore, all brand thiazide diuretics within the class reviewed are comparable to each other and to the generics and OTC products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand thiazide diuretic is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Dr. Yates commented that the use of thiazide diuretics in elderly patients often causes hyponatremia.

There were no further discussions on the agents in this class. Dr. Woodruff asked the P&T Committee Members to mark their ballots.

Thiazide-Like Diuretics: AHFS 402824
Manufacturer comments on behalf of these products:
None

Dr. Hisel stated that the thiazide-like diuretics that are included in this review are listed in Table 1. They are approved for the treatment of edema and hypertension. All of the agents are available in a generic formulation. There have been no major changes in the treatment guidelines, prescribing information, or clinical studies since this class was last reviewed.

Therefore, all brand thiazide-like diuretics within the class reviewed are comparable to each other and to the generics and OTC products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand thiazide-like diuretic is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Dr. Yates commented that metolazone may be more effective that other diuretics in patients with renal insufficiency.

There were no further discussions on the agents in this class. Dr. Woodruff asked the P&T Committee Members to mark their ballots.

Vasopressin Antagonists: AHFS 402828
Manufacturer comments on behalf of these products:
None

Dr. Hisel stated that the vasopressin antagonists that are included in this review are listed in Table 1. This is a new class review; however, tolvaptan was previously reviewed as a new drug by this committee in February 2010. Conivaptan is an injectable product which is FDA-approved to raise serum sodium in hospitalized patients with euvolemic and hypervolemic hyponatremia. Tolvaptan is an oral product that is approved for the treatment of clinically significant euvolemic and hypervolemic hyponatremia. There are no generic products currently available. There have been no major changes in the prescribing information, treatment guidelines or clinical studies since tolvaptan was last reviewed.

Therefore, all brand vasopressin antagonists within the class reviewed are comparable to each other and to the generics and OTC products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand vasopressin antagonist is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Dr. Woodruff asked how many requests there were for the vasopressin antagonists during the last year. Dr. Littlejohn commented that she did not have specific information regarding this at this time. Dr. Ferris stated that the number of requests may increase in the future as psychiatric patients with hyponatremia are discharged from the hospital. He asked if this patient population would be eligible to receive treatment with the vasopressin antagonists. Dr. Littlejohn stated that they would be eligible to receive these agents through the medical justification portion of the prior authorization process.

There were no further discussions on the agents in this class. Dr. Woodruff asked the P&T Committee Members to mark their ballots.

Diuretics, Miscellaneous: AHFS 402892
Manufacturer comments on behalf of these products:
None

Dr. Hisel stated that in July 2010, conivaptan and tolvaptan were moved from the miscellaneous diuretics class to the vasopressin antagonists class. Currently, there are no drugs classified by AHFS as miscellaneous diuretics.

No brand miscellaneous diuretic is recommended for preferred status. Alabama Medicaid should continue to include AHFS Class 402892 in the PDL screening process. If new outpatient miscellaneous diuretics are added, it is recommended that this class be re-reviewed at that time.

There were no further discussions on the agents in this class. Dr. Woodruff asked the P&T Committee Members to mark their ballots.

6. NEW DRUG REVIEWS (Please refer to the website for full text reviews.)

Intuniv® (guanfacine): AHFS 289200 – Central Nervous System Agents, Miscellaneous
Manufacturer comments on behalf of these products:
Intuniv® - Shire

Dr. Hisel stated that extended-release guanfacine was approved by the FDA for the treatment of ADHD in September 2009. The cerebral stimulants/agents used for ADHD were last reviewed by this committee in February 2010. Although the exact mechanism of action is unknown, it is thought that guanfacine stimulates post-synaptic alpha$_{2A}$-adrenergic receptors, which are involved in the modulation of attention and behavior. Guanfacine is not a cerebral stimulant; therefore, it is not a controlled substance and has no known potential for abuse or dependence. Extended-release guanfacine is not currently available in a generic formulation. Although immediate-release guanfacine tablets are available generically, these products are not FDA-approved for the treatment of ADHD. The extended-release product should not be substituted for immediate-release tablets on a mg-mg basis due to differences in their pharmacokinetic parameters.

Current treatment guidelines that incorporate the use of the cerebral stimulants/agents used for ADHD are summarized in Table 2. Guidelines recommend the use of cerebral stimulants for the initial treatment of children and adolescents with ADHD. Atomoxetine is recommended for patients with comorbid anxiety disorders, tics, sleep disorders, substance abuse, stimulant failure, or adverse events with stimulants. Immediate-release guanfacine is recommended as an alternative treatment option for ADHD. Extended-release guanfacine was approved by the FDA after the publication of the majority of these clinical guidelines.

There are several factors to take into consideration when selecting a pharmacologic agent for the treatment of children and adolescents with ADHD. This includes the presence of comorbid conditions, patient/family preference, storage/administration at school, history of substance abuse, drug diversion, pharmacokinetics and adverse events. The advantage of a once-daily formulation is that medication does not need to be taken during school hours, as is the case with immediate-release formulations. Administration of medications during school hours, especially Schedule II controlled substances, can be difficult since the medication must be administered by a licensed school nurse. Extended-release guanfacine is not a controlled substance, which may make it preferable to cerebral stimulants in certain situations.

The efficacy of extended-release guanfacine in the treatment of children and adolescents with ADHD is based on the results of three (8 to 9 week) placebo-controlled studies. Treatment with guanfacine showed greater improvements on ADHD rating scales than placebo. Two long-term, open-label, non-comparative studies have also demonstrated that extended-release guanfacine is safe and effective when administered to children and adolescents for up to 24 months. Extended-release guanfacine was also found to be safe and effective when added to existing cerebral stimulant therapy. There were no published studies found in the medical literature that directly

compared extended-release guanfacine to cerebral stimulants or atomoxetine. Efficacy beyond 9 weeks and safety beyond 2 years of treatment have not been established. Maintenance treatment has not been systematically evaluated and patients who are continued on longer-term treatment require periodic reassessment.

At this time, there is insufficient evidence to conclude that extended-release guanfacine offers a significant clinical advantage over other alternatives in general use. It should be available as adjunctive therapy through the medical justification portion of the prior authorization process.

No brand extended-release guanfacine product is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Dr. Ferris asked for clarification regarding the age of the patients in studies conducted with extended-release guanfacine. Dr. Hisel commented that this product was primarily studied in children and adolescents, and this is the patient population that it is FDA-approved for use in. Dr. Ferris asked if other treatments for ADHD are approved for use in adults. Dr. Hisel commented that other products are approved for use in adults.

Dr. Boothe commented that extended-release guanfacine may be appropriate for use in certain patient populations (i.e., in those at risk for substance abuse or when there is a need for a non-stimulant medication). She asked for clarification regarding the appropriate use of medical justification. Dr. Littlejohn stated that the Agency accepts substance abuse or the need for a non-stimulant medication as medical justification. She referred the members to the external criteria in the clinical packet.

Dr. Yates asked if the extended-release mechanism avoids problems with orthostatic hypotension. Dr. Hisel commented that orthostatic hypotension may still occur with the extended-release product. He also asked for clarification regarding the timing of administration. Dr. Hisel replied that the product is dosed once daily. Although a specific time is not listed in the package insert, most medications to treat ADHD are administered in the morning.

There were no further discussions on the agents in this class. Dr. Woodruff asked the P&T Committee Members to mark their ballots.

Ulesfia® (benzyl alcohol): AHFS 840412 – Scabicides and Pediculicides
Manufacturer comments on behalf of these products:
Ulesfia® - Shionogi Pharma

Dr. Hisel stated that benzyl alcohol lotion was approved by the FDA in April 2009 for the topical treatment of head lice infestation in patients 6 months of age and older. The skin and mucous membrane scabicides and pediculicides class was last reviewed in May 2009. Benzyl alcohol inhibits lice from closing their respiratory spiracles, which causes the lice to asphyxiate; however, it is not ovicidal. Therefore, a second treatment is required after 7 days to eradicate any lice that may have hatched since the first application. Benzyl alcohol lotion is not available in a generic formulation.

Current treatment guidelines that incorporate the use of the scabicides and pediculicides are summarized in Table 2. None of the available pediculicides are completely ovicidal, which requires applying the product at least twice at proper intervals. Resistance has also been reported with lindane, pyrethrins and permethrin. The American Academy of Pediatrics recommends the use of permethrin (1%) or pyrethrins as initial therapy, unless resistance to these products has been proven in the community. Benzyl alcohol (5%) or malathion (0.5%) can be used in areas where resistance to permethrin or pyrethrins has been demonstrated or for a patient who has failed to respond to either of these agents.

There were no published studies found in the medical literature evaluating the efficacy and safety of benzyl alcohol; however, according to the package insert, two phase III studies have been conducted. Benzyl alcohol eliminated all live lice in 76.2% and 75% of patients compared to 4.8% and 26.2% of patients receiving vehicle alone.

At this time, there is insufficient evidence to conclude that benzyl alcohol offers a significant clinical advantage over other alternatives in general use. It should be available as an alternative treatment option through the medical justification portion of the prior authorization process.

No brand benzyl alcohol product is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Mr. Main asked which pediculicide products are currently preferred. Dr. Hisel replied that malathion, permethrin and piperonyl butoxide/pyrethrins are preferred. Dr. Littlejohn stated that over-the-counter pediculicides are also preferred.

There were no further discussions on the agents in this class. Dr. Woodruff asked the P&T Committee Members to mark their ballots.

7. NEW BUSINESS

Thiazolidinediones: AHFS 682028
Manufacturer comments on behalf of these products:
None

Dr. Hisel stated that the thiazolidinedione class was last reviewed in May 2010. At that time, it was concluded that all brand thiazolidinediones were comparable to each other and did not offer a significant clinical advantage over other alternatives in general use. The recommendation that was approved by the committee was that no brand thiazolidinedione be recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands. Currently, Actos®, Avandia®, Avandamet®, and Avandaryl® are listed as preferred thiazolidinediones. There are no generic products available; however, metformin and glimepiride are available generically in a separate formulation.

On September 23, 2010, the FDA notified healthcare providers that it will significantly restrict the use of rosiglitazone in response to data that suggested an increased risk of cardiovascular events with the drug. They are requiring that the manufacturer develop a risk evaluation and mitigation strategy (REMS). Under the REMS, rosiglitazone will only be available to new patients if they are unable to achieve glycemic control on other antidiabetic agents and are unable to take pioglitazone. Current users of rosiglitazone will be able to continue taking the drug if they are benefiting from it. According to the FDA, "doctors will have to attest to and document their patients' eligibility; patients will have to review statements describing the cardiovascular safety concerns associated with this drug and acknowledge they understand the risks." The FDA also halted the TIDE trial, which was further evaluating the cardiovascular effects of rosiglitazone and pioglitazone in patients with type 2 diabetes. On September 17, 2010, the FDA also notified healthcare providers that they have begun a safety review of pioglitazone to further evaluate the risk of bladder cancer after receiving preliminary results from an ongoing, 10-year observational study. Five-year data suggests that there is no overall association between pioglitazone exposure and the risk of bladder cancer; however, there was an increased risk in patients with the longest exposure to the drug and in those receiving the highest cumulative dose. The safety review is ongoing and the FDA has not concluded that pioglitazone increases the risk of bladder cancer.

The thiazolidinediones are not recommended as initial therapy for the treatment of type 2 diabetes. They may be considered for dual or triple therapy, but they are frequently positioned lower than incretin mimetics and DPP-4 inhibitors due to their adverse event profiles. In comparative studies, the use of pioglitazone and rosiglitazone led to similar improvements in glycemic control. The fixed-dose combination products have been shown to improve glycemic control in patients with type 2 diabetes. However, there were no randomized studies found in the medical literature that directly compared the efficacy of the fixed-dose combination products to the coadministration of each component as separate formulations.

Pioglitazone and rosiglitazone may cause weight gain and fluid retention, as well as increase the risk for congestive heart failure and fractures. There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with the thiazolidinediones or any other antidiabetic drug. Since these agents are not recommended as first-line therapy for the treatment of type 2 diabetes mellitus, the thiazolidinediones should be managed through the medical justification portion of the prior authorization process.

Therefore, all brand pioglitazone-containing products within the class reviewed are comparable to each other and to the generics and OTC products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use. Rosiglitazone-containing products have a clinical disadvantage compared to the other brands, generics and OTC products in the class (if applicable).

No brand pioglitazone-containing product is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Rosiglitazone-containing products should not be placed in preferred status regardless of cost.

8. RESULTS OF VOTING ANNOUNCED

The results of voting for each of the therapeutic classes were announced; all classes were approved as recommended. Results of voting are described in the Appendix to the minutes.

9. NEXT MEETING DATE

The next P&T Committee Meeting is scheduled for 9:00 a.m. on February 9, 2011 at the Medicaid Building in the Commissioner's Board Room. Additional meetings will be held on May 11, 2011, August 10, 2011 and November 9, 2011.

10. ADJOURN

There being no further business, Mr. Main moved to adjourn, and Dr. Boothe seconded.

The meeting was adjourned at 10:49 a.m.

Appendix

RESULTS OF THE BALLOTING
Alabama Medicaid Agency
Pharmacy and Therapeutics Committee
November 10, 2010

A. Recommendation: No brand central alpha-agonist is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Medical Director	☑ Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Deputy Commissioner	☑ Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Commissioner	☑ Approve	☐ Approve as amended	☐ Disapprove	☐ No action

B. Recommendation: No brand direct vasodilator is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Medical Director	☑ Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Deputy Commissioner	☑ Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Commissioner	☑ Approve	☐ Approve as amended	☐ Disapprove	☐ No action

C. Recommendation: No brand peripheral adrenergic inhibitor is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

R Moore MD — ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Medical Director

Kathy Hall — ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner

[signature] — ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

D. Recommendation: No brand miscellaneous hypotensive agent is recommended for preferred status. Alabama Medicaid should continue to include AHFS Class 240892 in the PDL screening process. If new outpatient miscellaneous hypotensive agents are added, it is recommended that this class be re-reviewed at that time.

Amendment: None

Vote: Unanimous to approve as recommended

R Moore MD — ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Medical Director

Kathy Hall — ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner

[signature] — ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

E. Recommendation: No brand alpha-adrenergic blocking agent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Medical Director ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

Deputy Commissioner ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

Commissioner ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

F. Recommendation: No brand beta-adrenergic blocking agent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Medical Director ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

Deputy Commissioner ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

Commissioner ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

G. Recommendation: No brand dihydropyridine is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Medical Director	☑ Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Deputy Commissioner	☑ Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Commissioner	☑ Approve	☐ Approve as amended	☐ Disapprove	☐ No action

H. Recommendation: No brand miscellaneous calcium-channel blocking agent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Medical Director	☑ Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Deputy Commissioner	☑ Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Commissioner	☑ Approve	☐ Approve as amended	☐ Disapprove	☐ No action

I. **Recommendation:** No brand angiotensin-converting enzyme inhibitor is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Medical Director

☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner

☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

J. **Recommendation:** No brand angiotensin II receptor antagonist is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Medical Director

☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner

☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

K. Recommendation: No brand mineralocorticoid (aldosterone) receptor antagonist is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

R Moore MD — ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Medical Director

Kathy Hall — ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner

[signature] — ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

L. Recommendation: No brand renin inhibitor is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

R Moore MD — ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Medical Director

Kathy Hall — ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner

[signature] — ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

M. Recommendation: No brand loop diuretic is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

R Moore MD — ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Medical Director

Kathy Hall — ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner

[signature] — ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

N. Recommendation: No brand potassium-sparing diuretic is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

R Moore MD — ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Medical Director

Kathy Hall — ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner

[signature] — ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

O. Recommendation: No brand thiazide diuretic is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Medical Director ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

Deputy Commissioner ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

Commissioner ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

P. Recommendation: No brand thiazide-like diuretic is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Medical Director ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

Deputy Commissioner ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

Commissioner ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

Q. Recommendation: No brand vasopressin antagonist is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Medical Director ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

Deputy Commissioner ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

Commissioner ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

R. Recommendation: No brand miscellaneous diuretic is recommended for preferred status. Alabama Medicaid should continue to include AHFS Class 402892 in the PDL screening process. If new outpatient miscellaneous diuretics are added, it is recommended that this class be re-reviewed at that time.

Amendment: None

Vote: Unanimous to approve as recommended

Medical Director ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

Deputy Commissioner ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

Commissioner ☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

S. **Recommendation:** No brand extended-release guanfacine product is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Medical Director	☑ Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Deputy Commissioner	☑ Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Commissioner	☑ Approve	☐ Approve as amended	☐ Disapprove	☐ No action

T. **Recommendation:** No brand benzyl alcohol product is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Medical Director	☑ Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Deputy Commissioner	☑ Approve	☐ Approve as amended	☐ Disapprove	☐ No action
Commissioner	☑ Approve	☐ Approve as amended	☐ Disapprove	☐ No action

U. **Recommendation:** No brand pioglitazone-containing product is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Rosiglitazone-containing products should not be placed in preferred status regardless of cost.

Amendment: None

Vote: Unanimous to approve as recommended

☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

Medical Director

☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

Deputy Commissioner

☑ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

Commissioner

Respectfully submitted,

November 10, 2010

Tina Hisel, Pharm.D., BCPS